and public oncology centers in Brazil. **RESULTS:** Treatment was received by 161 eligible patients. The majority of patients were men (54.5%), and 30.3% were first diagnosed at stage IV. Across up to three lines of treatment, 76.4% received systemic therapy, 57.8% had surgery, 37.9% received radiotherapy and 9.3% received supportive care. Among first line treatment, 30.4% received systemic treatment only and 42.2% systemic in combination with surgery and/or radiotherapy. Second line treatment was administered to 67 patients; of those, 88.1% had systemic treatment, 9.0% received surgery, and 10.4% received radiotherapy. Only 26 patients received third line treatment. Outside clinical trial, the most commonly-used drug alone or in combination on first-line was Dacarbazine in both public (82.3%) and private (68.0%) systems, followed by Interferon in the public system (25.8%) and Interleukin in the private system (40.0%). The mean duration of systemic treatment was 17.6 (95% confidence interval (CI) 14.1-21.2) weeks. For second line, the most commonly-used drug was Paclitaxel (31.2%) for private system and Interferon and Paclitaxel (both 24.0%) for public system. Mean systemic treatment duration was 11.8 (95% CI 7.2-16.4) weeks. In third line, Fotemustine and Dacarbazine were the most commonly-used drugs. **CONCLUSIONS:** In Brazil the most common treatment for unresectable stage III and IV melanoma is systemic treatment combined with surgery and/or radiotherapy. The most comonly used agent in first line is Dacarbazine; most common second line treatments are Paclitaxel and Interferon.

MUSCULAR-SKELETAL DISORDERS - Clinical Outcomes Studies

PMS1

CHARACTERISTICS OF PATIENTS WITH RHEUMATOID ARTHRITIS IN TURKEY: RESULTS FROM THE TURKISH LEAGUE AGAINST RHEUMATISM RA REGISTRY

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OBJECTIVES: This study investigates the demographic and clinical characteristics of patients with rheumatoid arthritis (RA) in Turkey and attempts to inform strategies for the prevention, treatment, and support of RA. **METHODS:** In the present study, 2359 patients with RA from 43 centers across Turkey and who were listed in the Turkish League Against Rheumatism (TLAR) RA Registry were evaluated. Their demographic and clinical data were recorded. Disease activity, functional status, and radiographic damage were measured using the Disease Activity Score-28 (DAS-28), the Health Assessment Questionnaire (HAQ), and van der Heijde modified Sharp scoring method. Disease activity status was defined according to EULAR criteria. **RESULTS:** The mean age of the sample was 51.6 ± 12.5 years; 83.3% (1966) were women and 16.7% (393) were men. The mean duration of education was 5.22 ± 3.84 years, and 74.6% were homemakers. The mean disease duration was 11.9 ± 8.7 years. Exercise habits, smoking habits, and alcohol consumption were present in 7.1%, 16.2%, and 2.0%, respectively. The most common extra-articular signs were those involving the eye (4.8%). Co-morbid diseases were observed in 57.1% of the patients. Nonbiological disease-modifying anti-rheumatic drugs (DMARDs) were used by 91.0% of the patients, while 10.2% used biological DMARDs. The mean DAS-28, HAQ, and Sharp scores were 4.04 ± 1.46, 0.38 ± 0.37, and 31.25 ± 57.18, respectively. Patients who were in remission and had low disease activity rates comprised 17.8% and 14.1% of the sample respectively, while 42.7% and 25.5% had moderate and high disease activity rates, respectively. **CONCLUSIONS:** The majority of patients with RA in Turkey are middle-aged and homemakers. The level of education that important for compliance and success of treatment was low. Despite the high use of DMARDs, the majority of patients have moderate and high disease activities. This finding may suggest that the current treatment is insufficient.

PMS2

IMPROVEMENTS IN PHYSICAL FUNCTION AND DISABILITY IN PATIENTS WITH RHEUMATOID ARTHRITIS AFTER TREATMENT WITH NNC0109-0012 (ANTI-IL-20 MAB) IN A PHASE 2A TRIAL

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OBJECTIVES: To investigate the clinical efficacy of NNC0109-0012 (anti-IL-20 mAb) on physical function and disability in Rheumatoid Arthritis (RA) patients with active disease on stable MTX but inadequate response (MTX-IR) in a phase 2a multicentre, randomised, double-blind, placebo-controlled, parallel group trial. **METHODS:** Sixty-seven patients were randomised to once-weekly dosing of NNC0109-0012 (n=45) or placebo (n=22) for 12 weeks and followed for additional 13 weeks. Of the 67 randomised patients 43 were Rheumatoid Factor (RF)- and anti-Cyclic Citrullinated Protein (anti-CCP)-positive. Physical function and disability was assessed by the patient-reported outcome measure Health Assessment Questionnaire – Disability Index (HAQ-DI). HAQ-DI was assessed weekly from baseline to week 12 and additionally 3 times in the 13 weeks follow-up period. A mixed-effects model repeated measures was fitted to change in HAQ-DI score including treatment, time and interaction between treatment and time as fixed factors; baseline HAQ-DI score and interaction between time and baseline HAQ-DI score as continuous covariates and subject as random effect. **RESULTS:** Physical function was not significantly improved for NNC0109-0012 compared to placebo after end of treatment at 12 weeks (-0.26, p=0.130) for all randomised patients. In RF- and anti-CCP-positive patients physical function was significantly improved after both 12 and 25 weeks (p=0.047 and p=0.022, respectively). The estimated mean change in HAQ-DI for RF- and anti-CCP-positive patients at 12 and 25 weeks were -0.60 and -0.63 for NNC0109-0012, and -0.15 and -0.16 for placebo. The percentage of RF- and anti-CCP-positive patients that achieved the criteria for the minimum clinical important difference (HAQ-DI≥0.22 units) at 25 weeks was significantly higher (p=0.046) for the NNC0109-0012 treated patients compared to placebo with 76% (22 of 29 patients) versus 43% (6 of 14 patients). **CONCLUSIONS:** Treatment with NNC0109-0012 in MTX-IR RA patients on stable MTX effectively improved physical function and disability in RF- and anti-CCP-positive patients.

PMS3

IMPROVEMENTS IN PATIENT-REPORTED PAIN AND GLOBAL DISEASE ACTIVITY IN RHEUMATOID ARTHRITIS PATIENTS AFTER TREATMENT WITH NNC0109-0012 (ANTI-IL-20 MAB) IN A PHASE 2A TRIAL

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OBJECTIVES: To investigate the effects of NNC0109-0012 (anti-IL-20 mAb) on patient-reported pain and global disease activity in Rheumatoid Arthritis (RA) patients with active disease on stable MTX but inadequate response (MTX-IR) in a clinical phase 2a trial. **METHODS:** 67 patients were randomised to once-weekly dosing of NNC0109-0012 or placebo for 12 weeks and followed for 13 additional weeks. 43 patients were Rheumatoid Factor (RF)- and anti-CCP-positive. The level of pain and global disease activity was recorded on a 100 mm Visual Analogue Scale (VAS) by the patients and assessed weekly from baseline to week 12 and additionally 3 times in the 13 week follow up period. A mixed-effects model repeated measures was fitted to the change for each of the VAS scales including treatment, time and interaction between treatment and time as fixed factors; baseline VAS score and interaction between time and baseline VAS score as continuous covariates and subject as random effect. **RESULTS:** The average baseline pain and disease activity were 67 and 68 mm (NNC0109-0012) and 71 and 70 mm (placebo). In all randomised patients, pain was significantly reduced for NNC0109-0012 compared to placebo after 12 weeks with a mean difference of -15 mm (p=0.034) and was -13 mm (p=0.046) at week 25. Global disease activity was significantly lower in all randomised patients for NNC0109-0012 compared to placebo after 12 weeks with a mean difference of -17 mm (p=0.018) and maintained throughout the trial to week 25 with -14 mm (p=0.031). For both pain and global disease activity the effects were more pronounced in the RF- and anti-CCP-positive patients with a 1.5-2 fold larger difference in effect size compared to placebo than was observed for all randomised patients. **CONCLUSIONS:** Treatment with NNC0109-0012 (anti-IL-20 mAb) in MTX-IR RA patients on stable MTX improved both pain and global disease activity.

PMS4

COMPARING THE EFFICACY AND SAFETY OF BIOLOGICS FOR THE TREATMENT OF RHEUMATOID ARTHRITIS PATIENTS: A NETWORK META-ANALYSIS

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OBJECTIVES: Biologic therapy constitutes the current mainstay of rheumatoid arthritis (RA) patients treatment who have inadequately responded to methotrexate (MTX-IR). The objective of this study was to compare the relative efficacy, safety and tolerability of abatacept subcutaneous (sc) vs. all relevant comparators in MTX-IR patients with RA. **METHODS:** A systematic literature review identified clinical trials investigating the efficacy, safety and tolerability of abatacept intravenous and sc, adalimumab, certolizumab, etanercept, infliximab, golimumab, tocilizumab and anakinra in combination with MTX. The efficacy endpoints were: Health Assessment Questionnaire (HAQ) change from baseline (CFB), American College of Rheumatology (ACR) 20/50/70 response rates, and Disease activity score 28 joints (DAS28) remission rates defined as DAS28≤2.6, after 24 and 52 weeks of treatment. Safety and tolerability endpoints were: incidence of serious adverse events (AE), infections, serious infections, withdrawals for any reason, due to AE or due to lack of efficacy. Results were analysed using indirect treatment comparison methods estimating the expected relative effect of treatments, and were expressed as the difference in HAQ CFB and the Risk Ratio of achieving an outcome and associated 95% Credible Intervals. **RESULTS:** The analysis of HAQ CFB showed that abatacept sc is expected to show a relative efficacy comparable to other biologic. Furthermore, abatacept sc showed ACR20/50/70 response rates and DAS28 remission rates comparable to other biologic treatments at both time periods. Abatacept sc is expected to show a comparable safety and tolerability to other biologic treatments, having a similar incidence of serious AE, infections, serious infections, withdrawals for any reason, due to AE or due to lack of efficacy. **CONCLUSIONS:** Considering the assumptions of a NMA, abatacept sc is expected to produce similar HAQ CFB, ACR20/50/70 and DAS28 rates and a similar incidence of serious AE, infections, serious infections and withdrawals compared to other biologics in MTX-IR RA patients.

PMS5

BENEFIT-RISK ANALYSIS OF ADALIMUMAB AND ALTERNATIVE TREATMENTS FOR MODERATE-TO-SEVERE RHEUMATOID ARTHRITIS

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OBJECTIVES: To compare treatment-related risks versus improvements in outcomes in terms of net health benefit (NHB) for 3 treatments for moderate-to-severe rheumatoid arthritis: the anti–tumor necrosis factor drugs (anti-TNFs) adalimumab (ADA) and infliximab (IFX), both in combination with methotrexate (MTX), and MTX alone. **METHODS:** A simulation model was developed in which a cohort of rheumatoid arthritis patients initiating treatment progressed at 6-month intervals for 10 years or until withdrawal from therapy. NHB, measured in discounted qual-